

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P64961WO00 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/GB2004/005313 | International filing date (day/month/year) 17.12.2004 | Priority date (day/month/year) 22.12.2003 | |
| International Patent Classification (IPC) or national classification and IPC INV. A61L2/20 | | | |
| Applicant BIOQUELL UK LIMITED et al. | | | |

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| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 7 sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |
| <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application |

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| Date of submission of the demand 05.07.2005 | Date of completion of this report 27.03.2006 |
| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized officer Connor, M Telephone No. +49 89 2399-8402 |



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2004/005313

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-15 as originally filed

Claims, Numbers

1-9 as originally filed

Drawings, Sheets

1/3-3/3 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/005313

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

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|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-11 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-11 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
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Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 The present application does not meet the requirements of Article 6 PCT for the following reasons.
 - 1.1 Figures 1 and 5 are exactly the same, the former comprising text references and the latter numerical references. It is not understood, why Figure 1 could not comprise both numerical and text references and delete Figure 5 thus rendered redundant.
 - 1.2 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
 - 1.3 According to the requirements of Rule 10.2 PCT, the terminology and the signs shall be consistent throughout the application. This requirement is not met in view of the use of the expressions gas generator and internal aeration referred to as #21 and 40 in Figures 2 and 3, respectively and as 14 and 15 in Figure 5.
 - 1.4 The embodiments not falling within the ambit of present claim 1 should either be deleted or clearly identified as not belonging to the claimed invention (e.g., Figure 2).
 - 1.5 Claim 6 appears to be redundant with present claim 1, which amendments seem to be based on original claim 6.
- 2 The following documents were cited in the search report:
 - D1: US-A-5 229 071 (MEO, III ET AL) 20 July 1993 (1993-07-20)
 - D2: US-A-5 160 700 (ANDERSON ET AL) 3 November 1992 (1992-11-03)
 - D3: US 2003/086820 A1 (MCDONNELL GERALD E ET AL) 8 May 2003 (2003-05-08)
 - D4: US-A-3 503 703 (ROBERT L. MCDONALD ET AL) 31 March 1970 (1970-03-31)
 - D5: WO 03/082355 A (BIOQUELL UK LIMITED; ADAMS, NICHOLAS, MARK, TURNER; WATLING, DAVID) 9 October 2003 (2003-10-09)
- 3 The subject matter of claim 1 is considered to fulfil the requirements of Article 33 PCT

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.
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in terms of novelty, inventive step, and industrial applicability for the following reasons.

3.1 D1 and D4 disclose an enclosure for carrying out an operation under sterile conditions differing from the subject matter of present claim 1 in that *inter alia*, they comprise no plenum chamber, nor pump for said plenum chamber for delivering air into the plenum chamber and to the main chamber to create a filtered flow of air. D4 may probably be considered as closest prior art as it discloses a multichamber apparatus comprising a flexible sterilization chamber (12) connected to a chamber (70) comprising sterilant in fluid communication with a chamber (60) comprising a fan (58). Said chamber (60) is in fluid communication

- (a) via a filter (64) with an outlet chamber (62) filled with a gas sorbing agent (65) and comprising an outlet (67), and
- (b) via a filter (90) with a chamber (87), which connects to the flexible chamber (12).

The apparatus disclosed in D4, however, is based on a different principle than the one called for in present claim 1. Filtered air is introduced into inlet (49), is filtered in (50) and (55), before being introduced into the flexible chamber (12) where it is sucked back into duct (29), through filter (90) into chamber (60) wherein it closes the cycle by passing through chamber (70) where it picks up sterilant vapour and is turned back into flexible chamber (12) through filter (55) and duct (28). After several such cycles, the air is released through filter (64) into chamber (62) filled with gas sorbing agent (65) and released via outlet (67).

In the apparatus called for in present claim 1, air is introduced into and evacuated from the main chamber through the plenum chamber. There is no way the skilled person starting from D4 could arrive at the subject matter of present claim 1 without involving an inventive step (or without hindsight). The subject matter of present claim 1 can therefore be considered as inventive in the sense of Article 33(3) PCT.